

Serial No.: 10/027,226

Confirmation No.: 9039

Filed: 20 December 2001

For: METHODS AND DEVICES FOR REMOVAL OF ORGANIC MOLECULES FROM BIOLOGICAL MIXTURES USING A HYDROPHILIC SUPPORT IN A HYDROPHOBIC MATRIX

Remarks

The Office Action mailed 3 July 2003 has been received and reviewed. Claims 56-61 having been canceled, claims 1, 18, 20, 24, 26-28, 46-47, and 50 having been amended, and claims 62-77 having been added, the pending claims are claims 1-55 and 62-77. Of the pending claims, claims 1-49 have been withdrawn from consideration.

The paragraph beginning at page 23, line 6 of the specification has been amended to correct a typographical error and to delete reference numerals 20, 30, and 40, which are not illustrated in Figure 1. The paragraph beginning at page 24, line 6 has been amended to correct a typographical error, thereby correctly reciting "loading chamber 62," which is supported, for example, by Figure 1 and the specification at page 23, lines 22-23.

Claim 50 has been amended to move recitations from the preamble to the body of the claim. Claim 50 has been further amended to recite "at least one distribution channel connecting the plurality of process chambers of the array," an amendment which is intended to clarify the claim, however the scope of the claim is intended to be the same or broader after the amendment as it was before the amendment. Finally, language in claim 39 has been cosmetically amended (i.e., "wherein at least one of the process arrays comprises a solid-phase extraction material within the array"). Method claims 1, 20, 26, 28, and 47 have been amended to incorporate recitations from device claim 50. Claims 18, 24, 27, and 46 which depend from claims 1, 20, 26, and 28, respectively, have been cosmetically amended in accordance with claims 1, 20, 26, and 28, respectively (as amended). New claims 62-77 are supported, for example, by claim 50 and originally filed claims 3-18, respectively.

Reconsideration and withdrawal of the rejections are respectfully requested.

Affirmation of Provisional Election

Applicants thank the Examiner for withdrawing the Election of Species requirement. In the Office Action mailed 3 July 2003, the Examiner issued a rewritten

Restriction Requirement under 35 U.S.C. §121 in the above-identified application, grouping the claims as follows: Group I, claims 1-49 drawn to methods of removing small negatively charged particles from a sample, Group II, claims 50-55, drawn to a device for removing small negatively charged particles from a sample, and Group III, claims 56-61, drawn to a container with an adhesive cover for removing small negatively charged particles from a sample. Applicants hereby affirm, with traverse, the election to prosecute claims 50-55, Group II.

Specifically, Applicants respectfully request that the Examiner reconsider the restriction requirement and rejoin Group II (claims 50-55, drawn to a device) with Group I (claims 1-49, as amended, drawn to methods of using a device). Applicants respectfully submit that the inventions as claimed can be readily evaluated in one search without placing undue burden on the Examiner.

Obviousness-Type Double Patenting Rejection

Claims 50-53 were provisionally rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 53 and 56-58 of copending U.S. Pat. Application Serial No. 10/417,609 and in view of U.S. Pat. No. 6,451,260 (Dusterhoft et al.). Claims 50-53 were also provisionally rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 39-42 of copending U.S. Pat. Application Serial No. 10/027,222 in view of U.S. Pat. No. 6,451,260 (Dusterhoft et al.). Upon an indication of otherwise allowable subject matter and in the event this rejection is maintained, Applicants will provide an appropriate response. In the event that the provisional obviousness-type double patenting rejections are the only rejections remaining in the present application, Applicants respectfully request that the Examiner withdraw the provisional rejection and allow the application to issue as a patent pursuant to M.P.E.P. §804(I)(B).

Rejection under 35 U.S.C. §103

The Examiner rejected claims 50-53 under 35 U.S.C. §103(a) as being unpatentable over U.S. Pat. No. 6,344,326 (Nelson et al.) in view of U.S. Pat. No. 6,451,260 (Dusterhoft et al.). Applicants respectfully traverse the rejection.

"To establish a *prima facie* case of obviousness . . . there must be some suggestion or motivation, either in the references themselves or in the knowledge generally available to one of ordinary skill in the art, to modify the reference or to combine reference teachings." M.P.E.P. §706.02(j). "If the proposed modification or combination of the prior art would change the principle of operation of the prior art invention being modified, then the teachings of the references are not sufficient to render the claims *prima facie* obvious." M.P.E.P. §2143.01. Applicants respectfully submit that the Examiner has failed to establish a *prima facie* case of obviousness.

Nelson et al. disclose "[i]ntegrated microfluidic devices comprising at least an enrichment channel (10) and a main electrophoretic flow-path (12). . . . In the subject integrated devices, the enrichment channel and the main electrophoretic flowpath are positioned so that waste fluid flows away from said main electrophoretic flowpath through a discharge outlet (6)." (Abstract). However, Nelson et al. lack, among other things, a disclosure or suggestion of a device that includes a plurality of process arrays wherein at least one of the process arrays comprises a solid-phase extraction material within the array; wherein the solid-phase extraction material comprises *a hydrophilic solid support at least partially embedded within a hydrophobic matrix* (e.g., present independent claim 50).

Dusterhoft et al. disclose "methods for producing microporous elements and microporous elements obtainable by such methods" (Abstract). Dusterhoft et al. disclose methods that use a resin, which, "[i]n certain instances, the resin preferably comprises both hydrophilic and hydrophobic segments within its molecules" (column 10, lines 31-32), to

"provide the benefit of biocompatibility" (column 11, line 34). However, Dusterhoft et al. lack, among other things, a device comprising: *a plurality of process arrays*, wherein each process array of the plurality of process arrays comprises: *a plurality of process chambers*, each of the process chambers defining a volume for containing a biological sample mixture; and *at least one distribution channel connecting the plurality of process chambers of the array*; wherein *at least one of the process arrays comprises a solid-phase extraction material within the array* (e.g., present independent claim 50).

Thus, Applicants respectfully submit that one of skill in the art would have no motivation to combine Nelson et al., which discloses devices useful for conventional elution methods, with the polymers disclosed by Dusterhoft et al., which were described as being useful to provide the benefit of biocompatibility, to arrive at the presently claimed invention (e.g., claims 50-53).

Furthermore, the present invention discloses a device that is operable to *remove small negatively charged organic molecules* from a biological sample mixture (e.g., independent claim 50). As described in the present specification, "removal" of unwanted molecules involves adhering such molecules to the solid-phase material and allowing desirable products to remain in solution. This is in contrast to conventional elution methods that involve adhering the desirable products to the solid-phase material, washing away the unwanted molecules, and eluting the desirable products to remove them from the solid-phase material." (Specification at page 4, line 28 to page 5, line 2).

In contrast to the present invention, Nelson et al. suggest the use of ion exchange resins as "[s]uitable capture media for proteins" (column 8, lines 16-18). In short, Nelson et al. suggest conventional elution methods that involve that involve adhering the desirable products (e.g., proteins, column 8, lines 16-18) to the solid-phase material (e.g., ion exchange resins; column 8, lines 16-18), (i.e., "enrichment;" column 2, lines 53-57), washing away the unwanted molecules (e.g., "waste fluid flows away from said main electrophoretic flowpath through a

discharge outlet;" Abstract), and eluting the desirable products to remove them from the solid-phase material (e.g., "subsequent movement through the main electrophoretic flowpath;" column 2, lines 57-58).

Applicants respectfully submit that combining the polymers including hydrophilic and hydrophobic segments to provide the benefit of biocompatibility, as disclosed by Dusterhoft et al., with the devices disclosed by Nelson et al. would change the principle of operation of the Nelson et al. devices. Specifically, the devices disclosed by Nelson et al. include suitable capture media, and operate by conventional elution methods that involve adhering the desirable products to the solid-phase material. The Examiner urges that the Nelson et al. devices be modified to include polymers including hydrophilic and hydrophobic segments as disclosed by Dusterhoft et al. However, Applicants respectfully submit that if the modification arguably resulted in devices operable to *remove small negatively charged organic molecules* from a biological sample mixture (e.g., independent claim 50), then the devices would no longer operate by using capture media to adhere desirable products to the solid-phase material, thus changing the principle of operation of the Nelson et al. devices. In view of the remarks presented herein above, Applicants respectfully submit that Nelson et al. in view of Dusterhoft et al. is not sufficient to render the present claims (e.g., claims 50-53) *prima facie* obvious.

Moreover, Nelson et al. in view of Dusterhoft et al. fail to disclose or suggest preferred embodiments of the present invention including, for example, a device as disclosed in claim 50 further including a plurality of valves (e.g., claim 51), a plurality of independent process arrays (e.g., claim 52), or a plurality of process arrays arranged radially on the device (e.g., claim 53).

For at least the reasons presented herein above, Applicants respectfully submit that claims 50-53 are patentable over Nelson et al. in view of Dusterhoft et al.

The Examiner rejected claims 54 and 55 under 35 U.S.C. §103(a) as being unpatentable over U.S. Pat. No. 6,344,326 (Nelson et al.) in view of U.S. Pat. No. 6,451,260

(Dusterhoft et al.) as applied to claims 50-53 above, and further in view of U.S. Pat. No. 4,399,009 (Chisholm). Applicants respectfully traverse the rejection.

The deficiencies of Nelson et al. in view of Dusterhoft et al. have been described in the remarks presented herein above in response to the rejection of claim 50. Applicants respectfully submit that Chisholm, which relates to an "electrolytic cell and method" (title), fails to cure the deficiencies of Nelson et al. in view of Dusterhoft et al.

Thus, Applicants respectfully submit that claims 54 and 55, which depend from claim 50, are patentable over Nelson et al. in view of Dusterhoft et al. further in view of Chisholm for at least the reasons presented herein above.

In view of the remarks presented herein above, Applicants respectfully request that the Examiner reconsider and withdraw the rejections under 35 U.S.C. §103.

New Claims

New claims 62-77 depend from claim 50. For at least the reasons presented herein above for the patentability of independent claim 50, Applicants respectfully submit that new claims 62-77 are also patentable. Applicants respectfully request that the Examiner consider and pass new claims 62-77 on to allowance.

Information Disclosure Statement

Applicants originally submitted an Information Disclosure Statement on 26 April 2002. In a telephone conversation on 22 July 2003, the Examiner indicated that the documents listed on pages 3 and 4 of the 1449 forms could not be located. Applicants are submitting herewith clean copies of pages 3 and 4 of the 1449 forms, a copy of the Information Disclosure Statement submitted on 26 April 2002, copies of the documents listed on pages 3 and 4 of the 1449 forms, and a stamped postcard indicating receipt of the documents by the United States Patent and Trademark Office. Pursuant to the provisions of M.P.E.P. §609, Applicants further



Amendment and Response

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request that a copy of the 1449 form(s), marked as being considered and initialed by the Examiner, be returned with the next Official Communication.

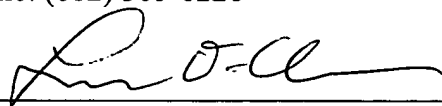
Summary

It is respectfully submitted that all the pending claims are in condition for allowance and notification to that effect is respectfully requested. The Examiner is invited to contact Applicants' Representatives, at the below-listed telephone number, if it is believed that prosecution of this application may be assisted thereby.

Respectfully submitted for
PARTHASARATHY et al.

By
Muetting, Raasch & Gebhardt, P.A.
P.O. Box 581415
Minneapolis, MN 55458-1415
Phone: (612) 305-1220
Facsimile: (612) 305-1228

October 3, 2003
Date

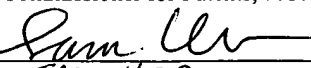
By: 
Loren D. Albin
Reg. No. 37,763
Direct Dial (612)305-1225

CERTIFICATE UNDER 37 CFR §1.10::

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Date of Deposit: October 3, 2003

I hereby certify that the Transmittal Letter and the paper(s) and/or fee(s), as described hereinabove, are being deposited with the United States Postal Service "Express Mail Post Office to Addressee" service under 37 CFR §1.10 on the date indicated above and is addressed to the Assistant Commissioner for Patents, P.O. Box 1450, Alexandria, VA 22313-1450.

By: 
Name: SAM HER
